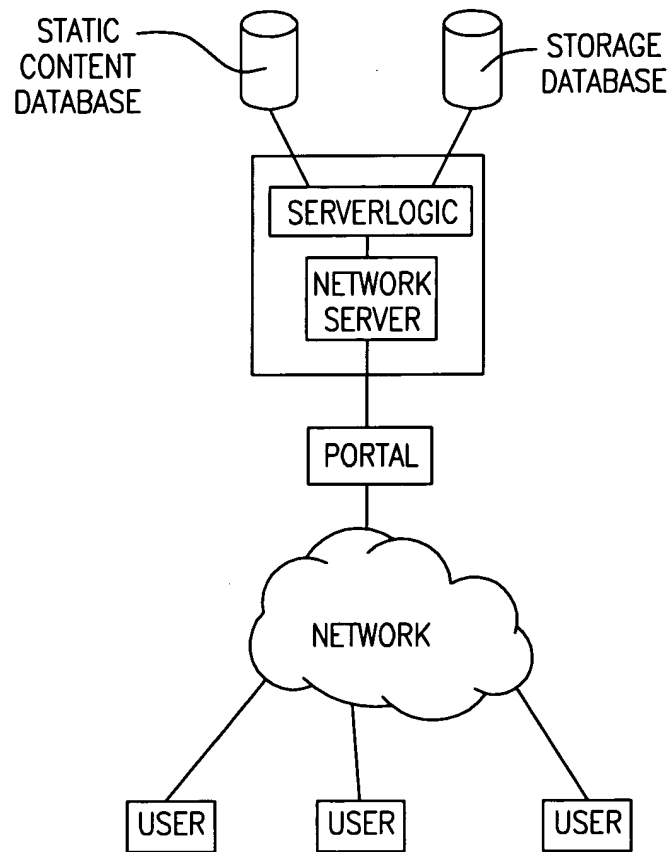


*FIG. 1*



*FIG. 2*

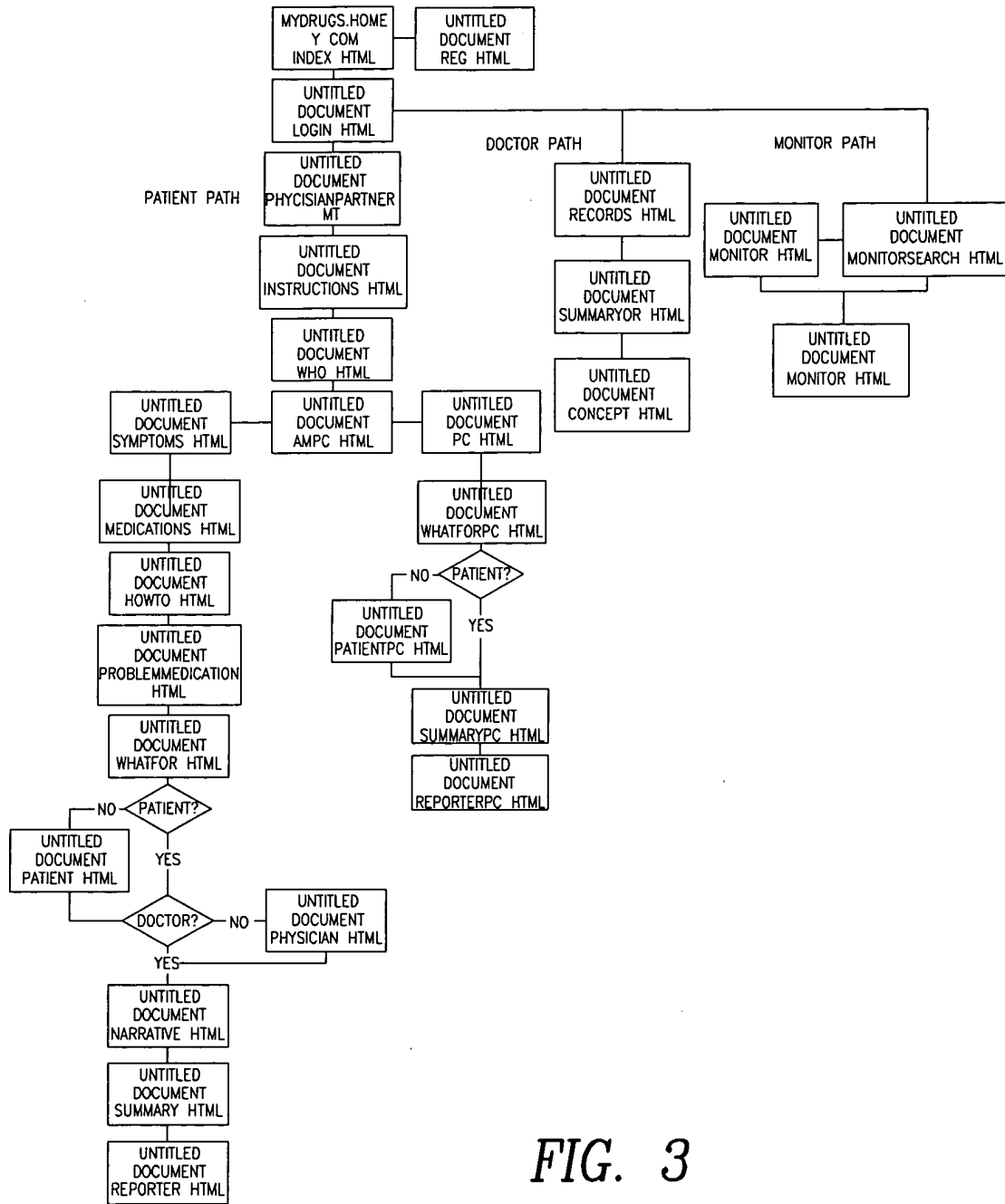


FIG. 3

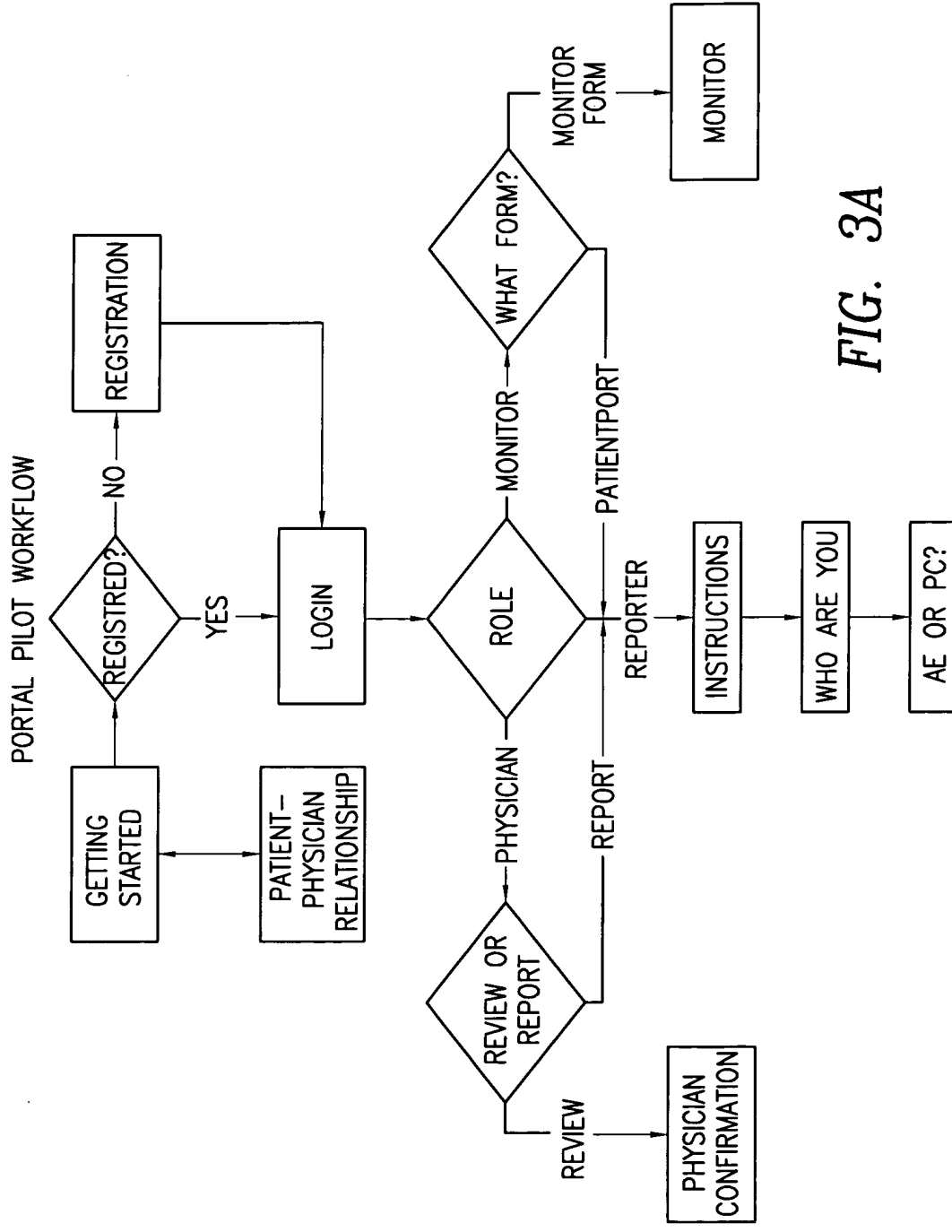
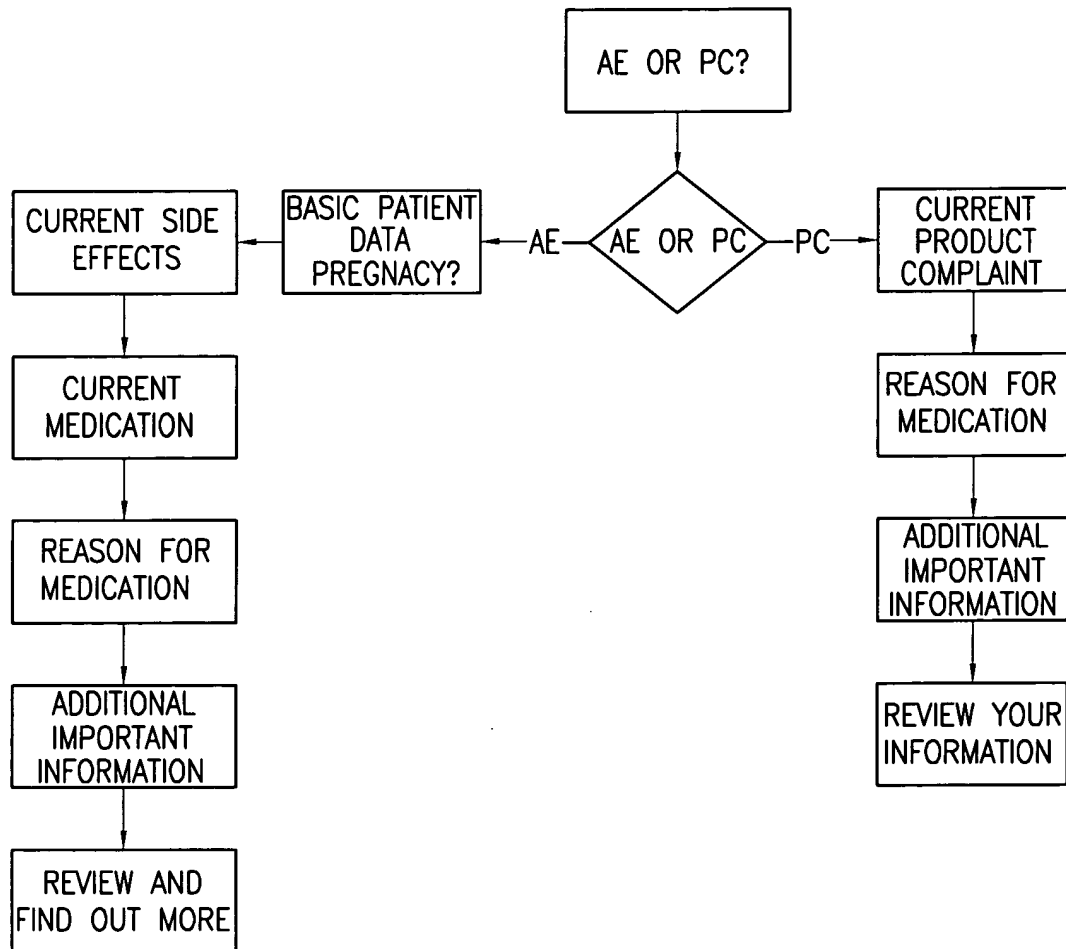


FIG. 3A

AE OR PC  
GUIDED REPORTING



*FIG. 3B*

# PHYSICIAN CONFIRMATION

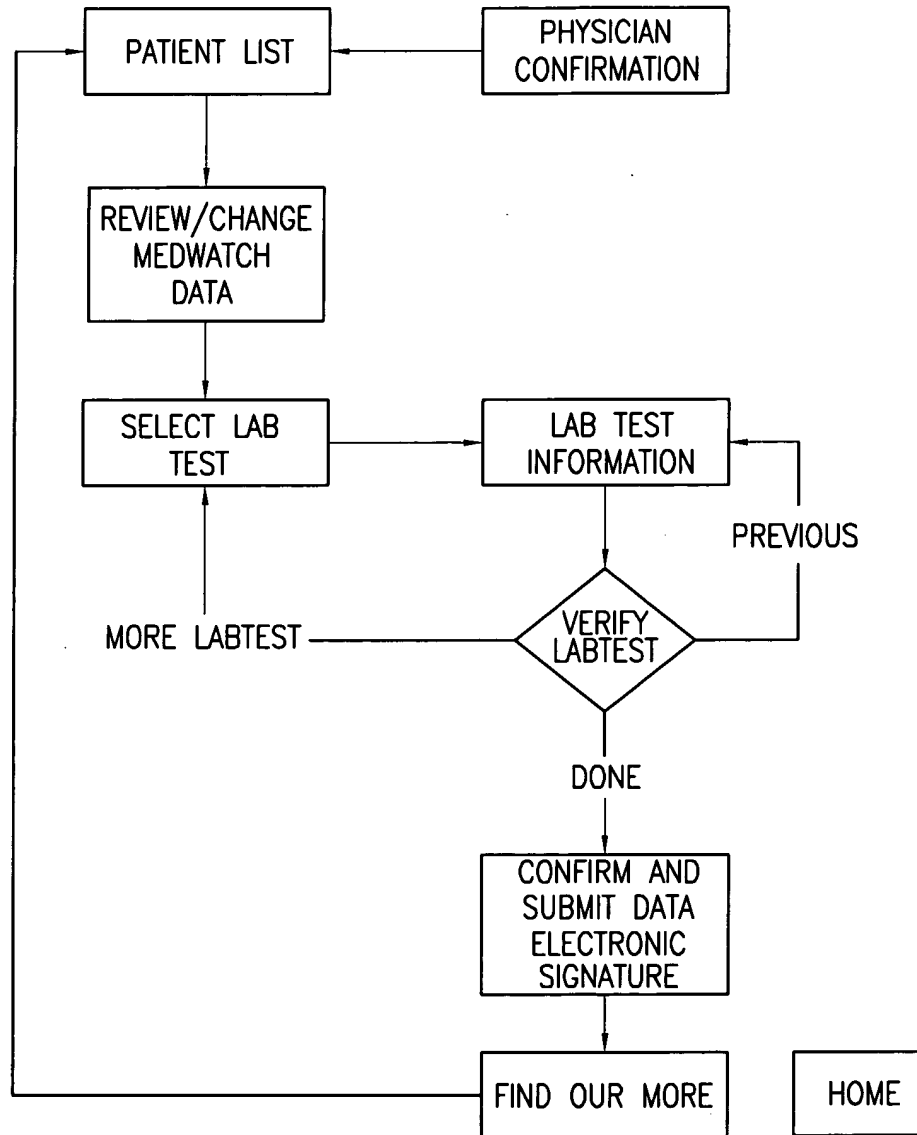


FIG. 3C

# MONITOR FORM

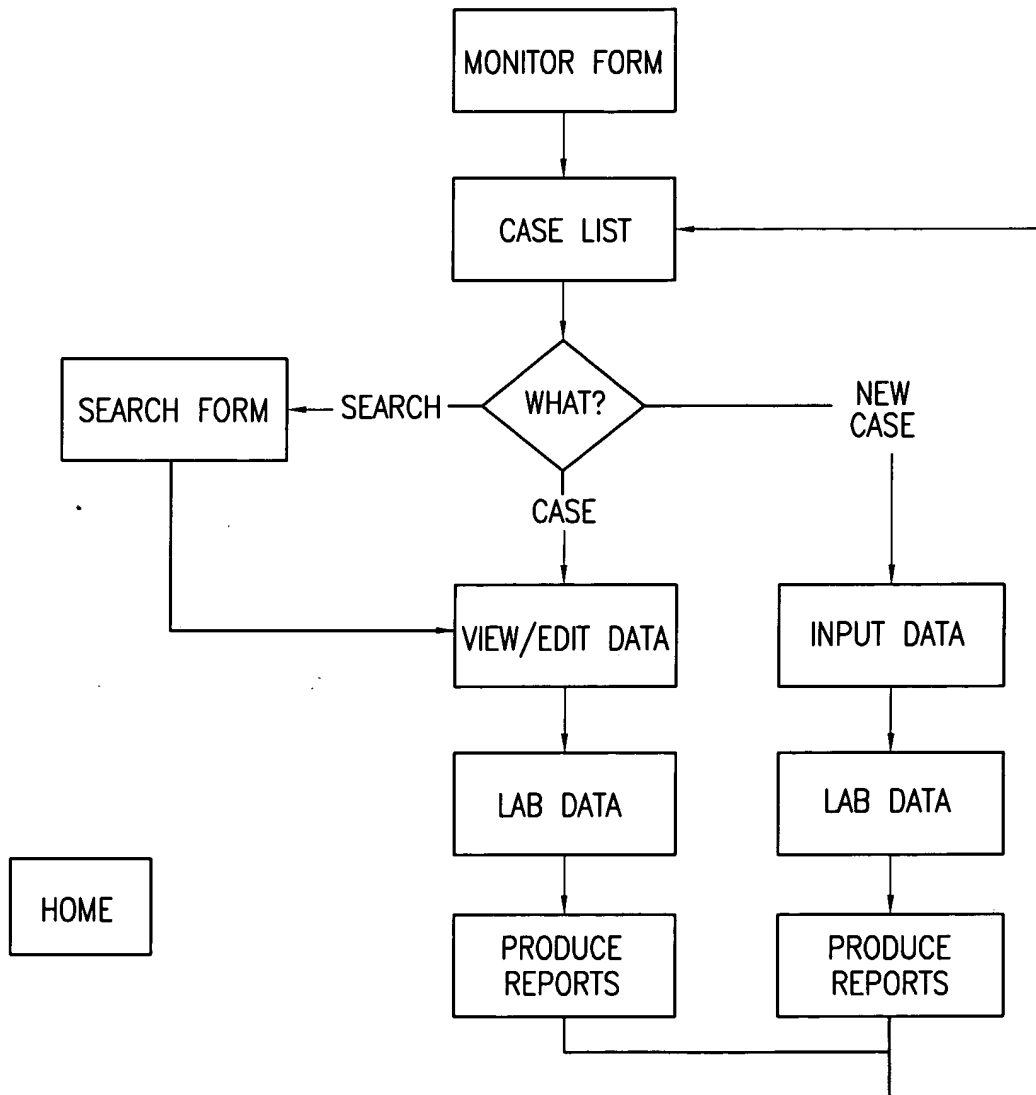
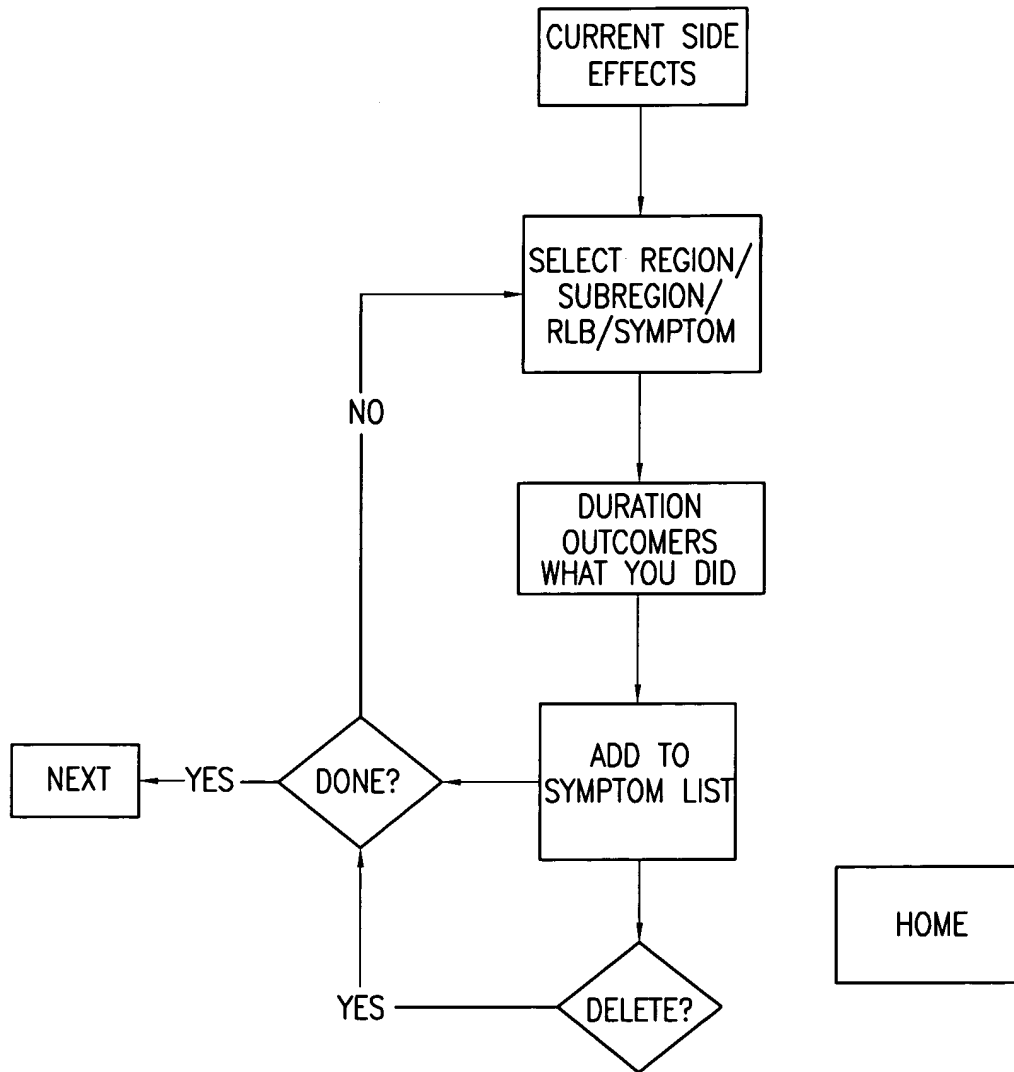


FIG. 3D

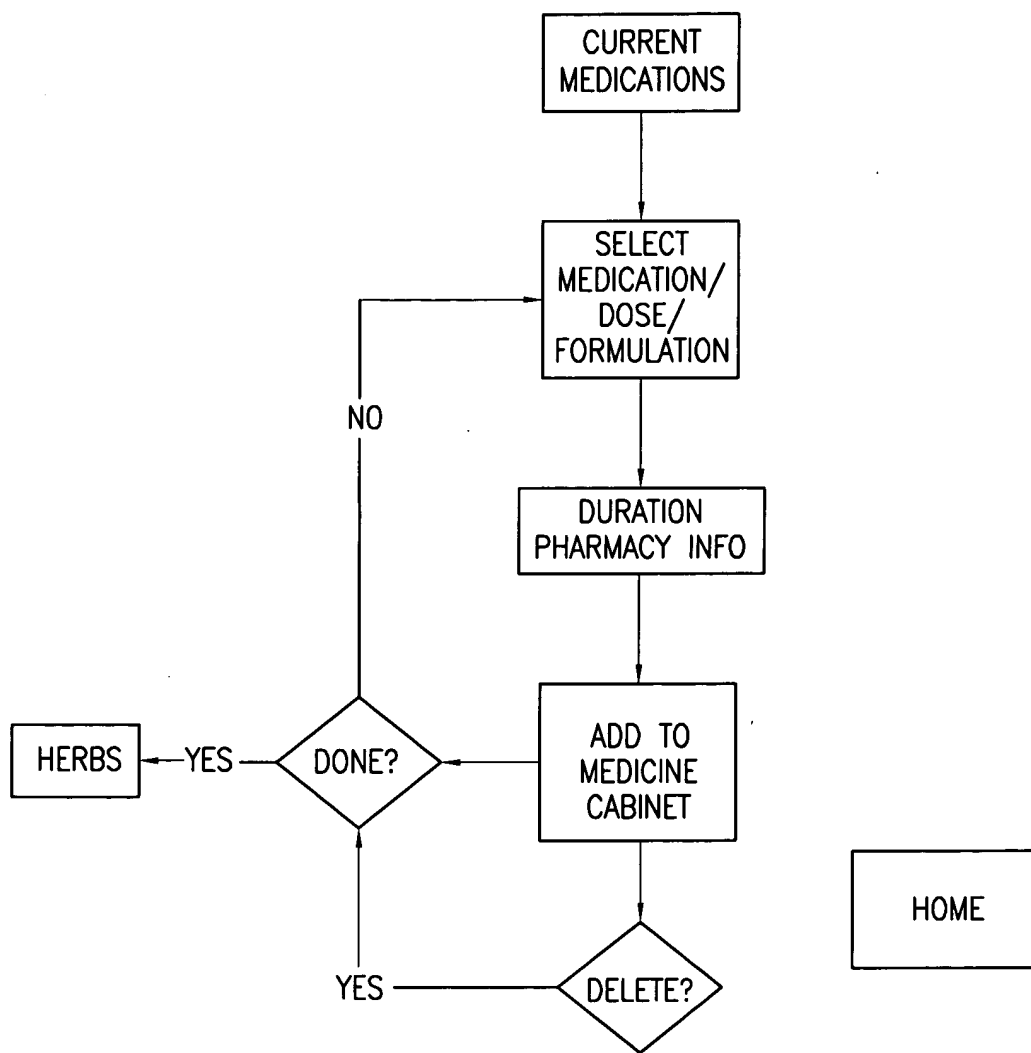
# CURRENT SIDE EFFECTS



*FIG. 3E*

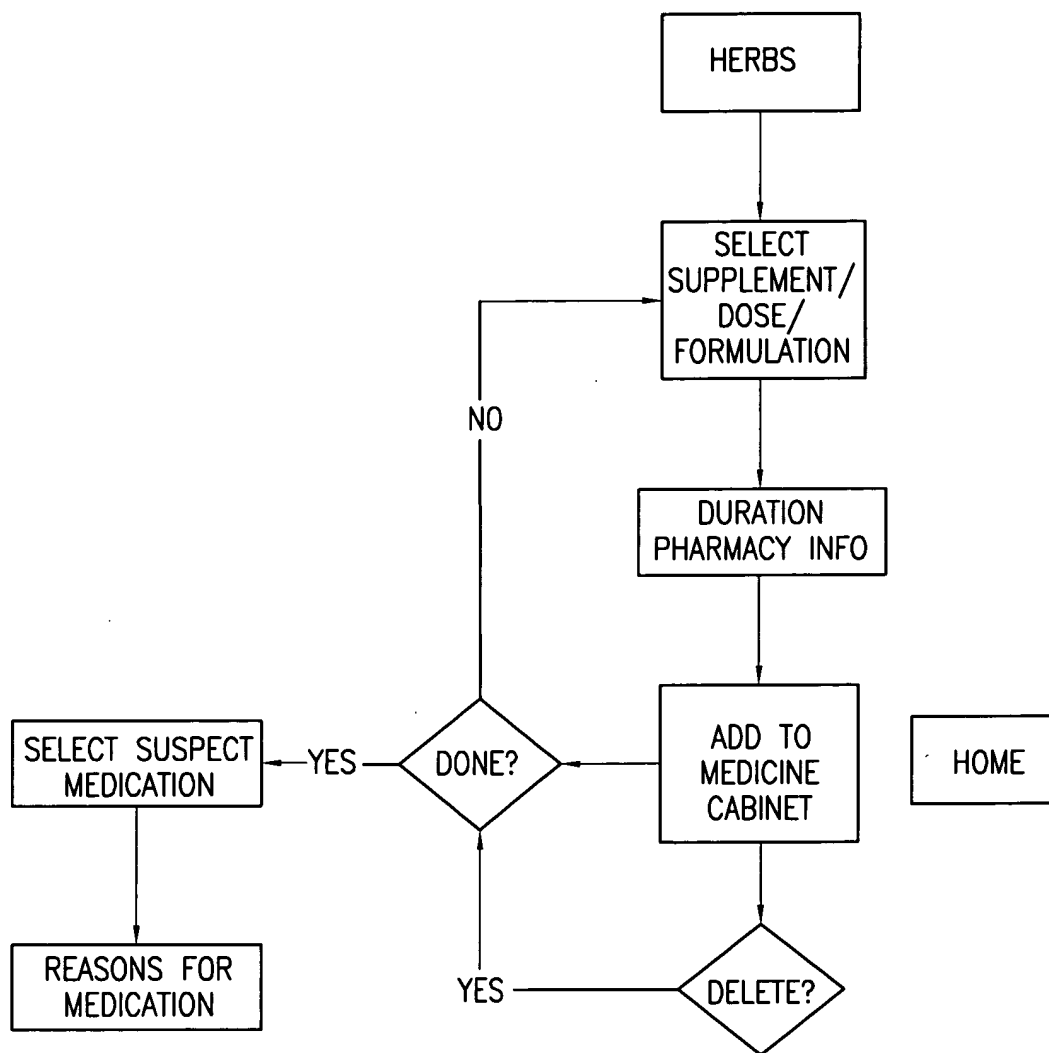


# CURRENT MEDICATION



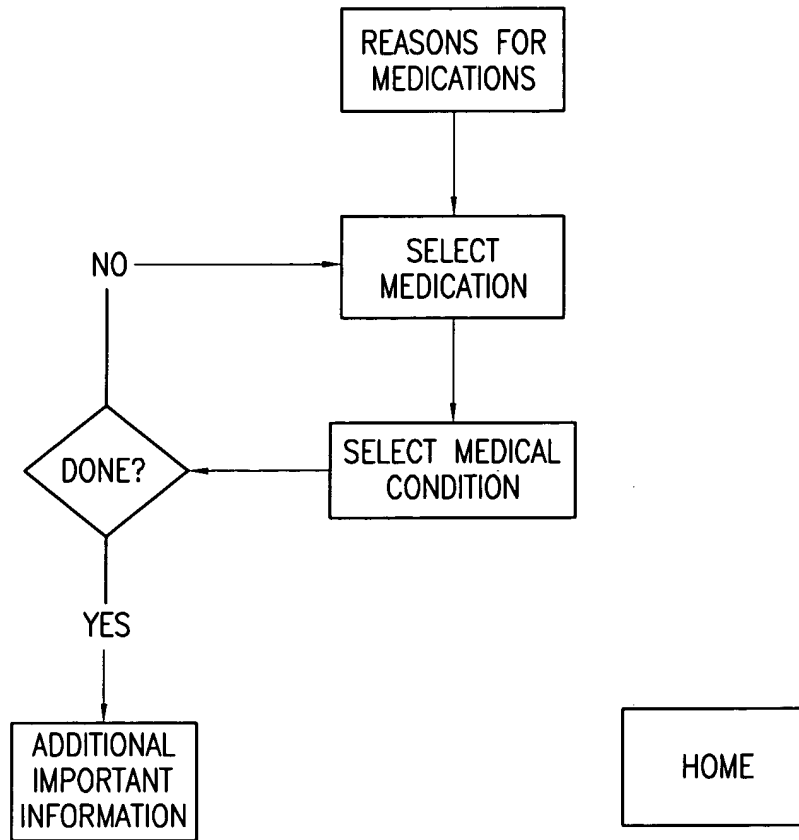
*FIG. 3F*

## HERBS AND NUTRITIONAL SUPPLEMENTS



*FIG. 3G*

# REASONS FOR MEDICATION



*FIG. 3H*

# ADDITIONAL IMPORTANT INFORMATION

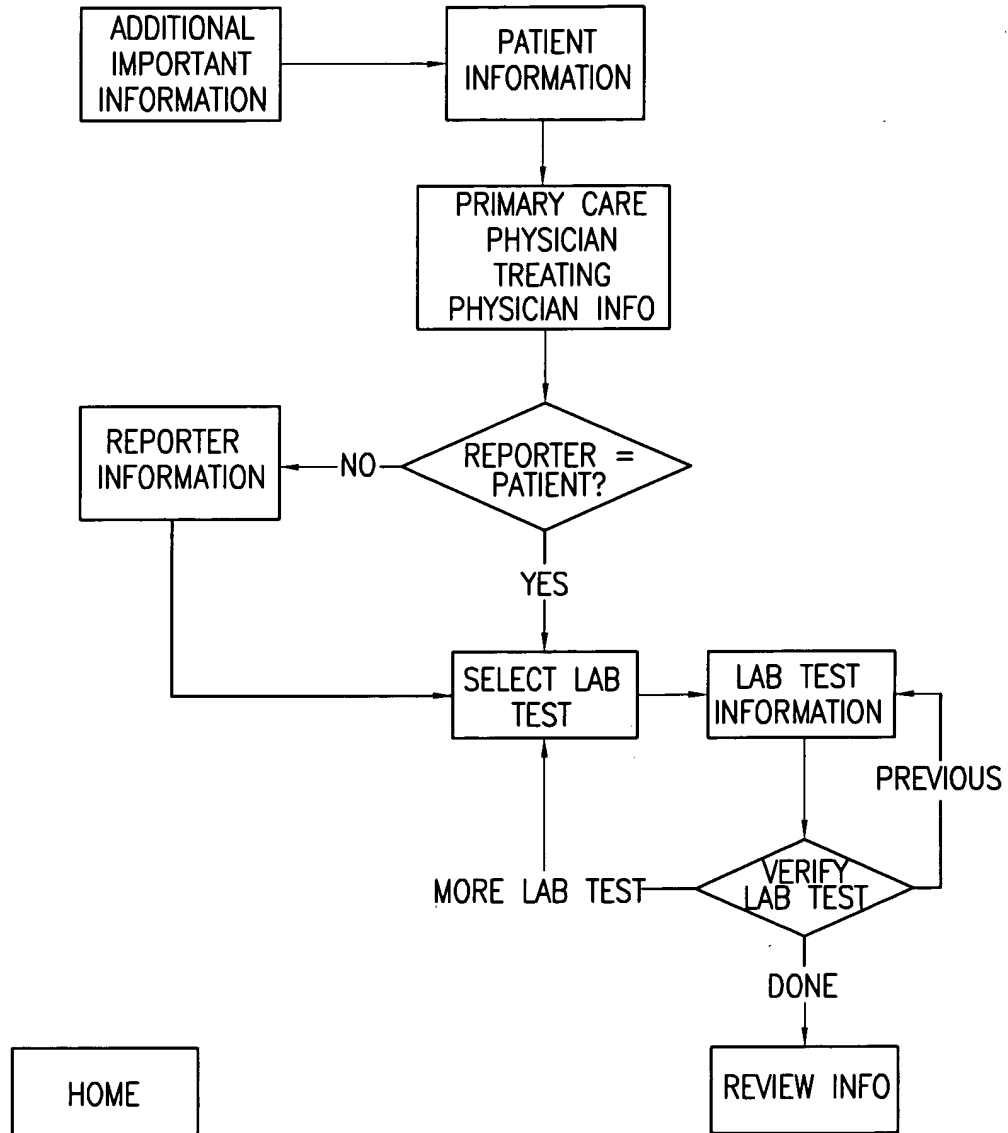
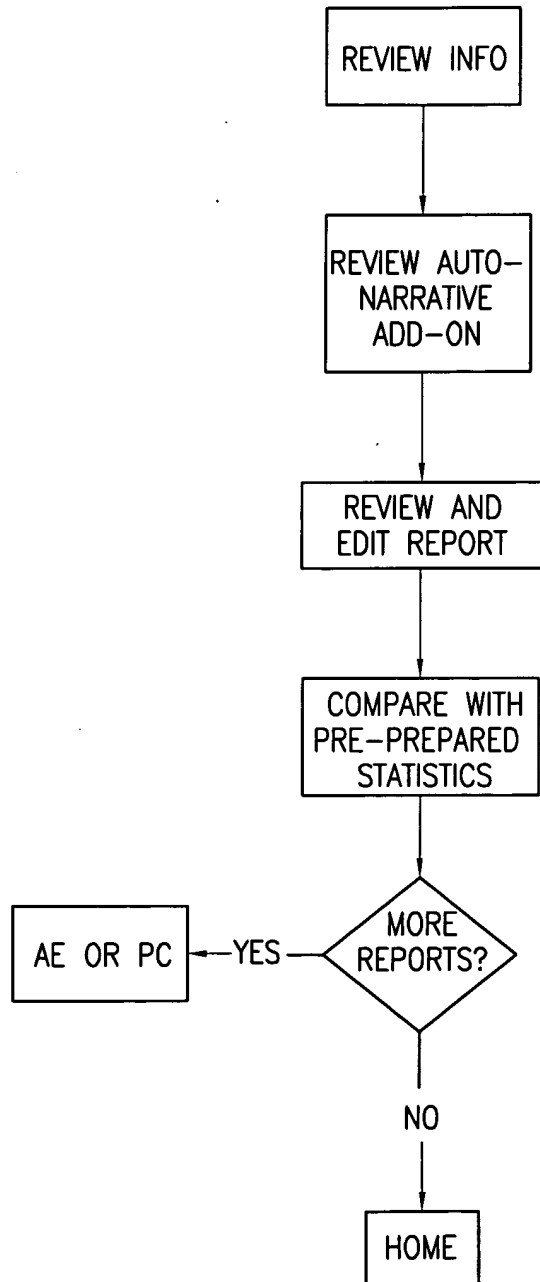


FIG. 3I

REVIEW INFORMATION AND FIND OUT MORE



*FIG. 3J*

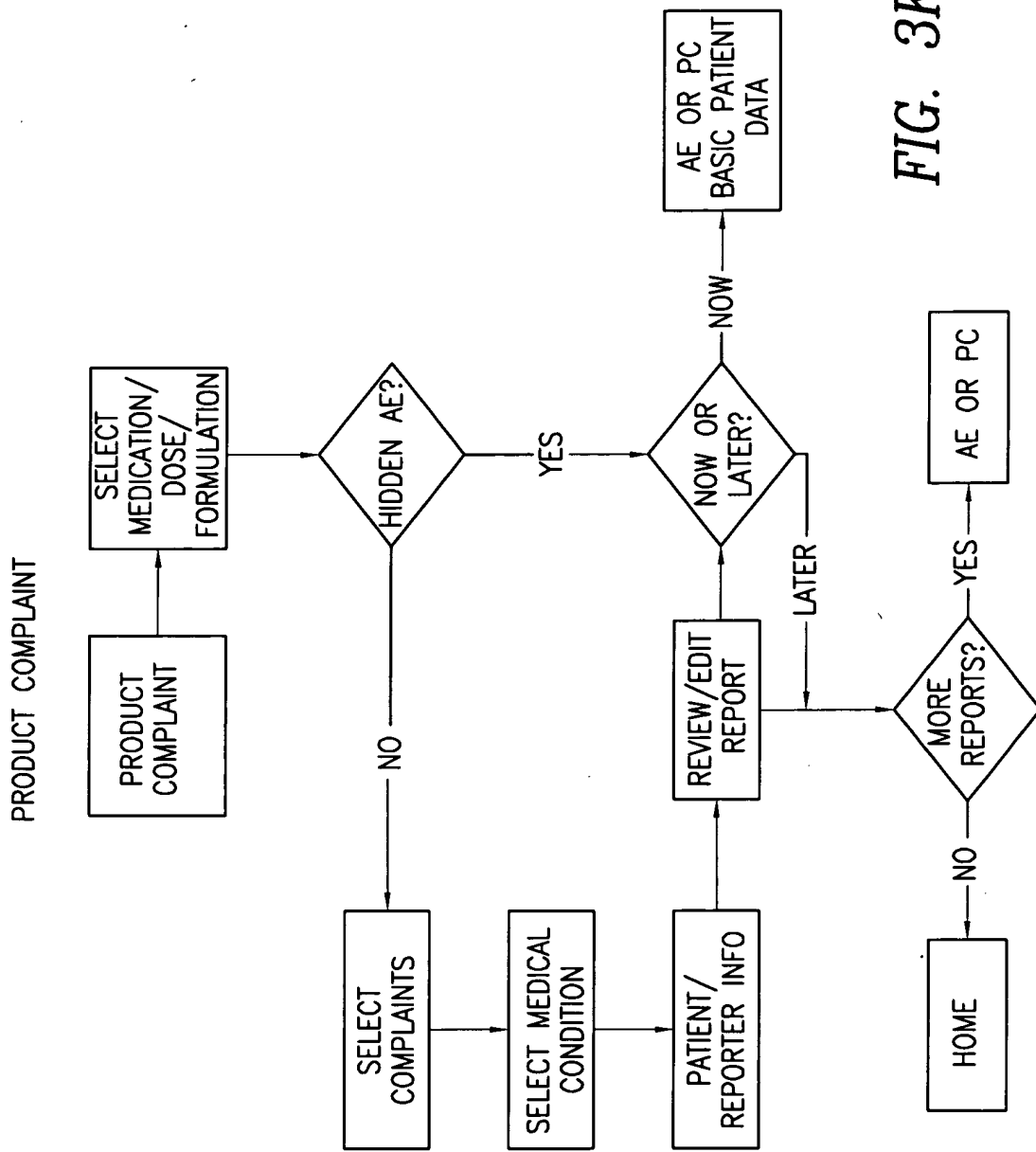
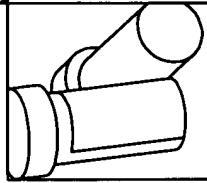


FIG. 3K



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Registration

## INFORMED CONSENT

IN ORDER TO COMPLETE THE REPORT, WE MAY NEED TO CONTACT YOUR PHYSICIAN. YOUR CONSENT TO CONTACT your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ Accept (required to proceed)

## 1 Getting Started Login/Registration instructions

Who are you  
Side Effects and/or  
Product Complaints

This web portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can recreate it: 1)define a secret question (ex: What is my favorite football team) 2)define a secret answer (ex: the SF 49ers). Together these will identify you.

for this pilot, type the 8 digit registration code printed on your trial card.  ?

First Name

Last Name

User ID

Password

Password again

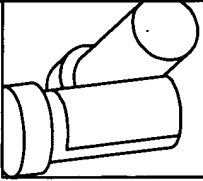
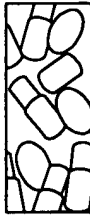
Secret Question

Secret Answer

Phone Number

E-mail

FIG. 4



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Welcome to MyDrug Safety

## Getting Started

First-time user? Go to our registration page.

### 1 Getting Started Login/Registration instructions

Who are you  
Side Effects and/or  
Product Complaints

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easysteps. At the end, you will receive a summary report for review.

the (?) symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

## userID and Password (?)

User ID

Password

### Change your Password?

New Password

Repeat Password

FIG. 5

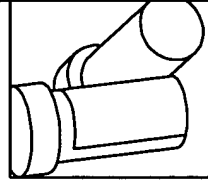




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Patient-Physician Relationship



**1** Getting Started  
Login/Registration  
instructions

Who are you  
Side Effects and/or  
Product Complaints

### The Patient/Physician Relationship

②

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear

Recover

FIG. 6

1

Getting Started  
 Login/Registration  
 instructions  
 Who are you  
 Side Effects and/or  
 Product Complaints

Easy steps to report a Side Effect or Adverse Event

- STEP 1:

Side effect or you are experiencing
- STEP 2:

Medications you are taking
- STEP 3:

Reasons for medication
- STEP 4:

Additional important information
- STEP 5:

review your report and find out more

Easy steps to report a Product Complaint

- STEP 1:

Product complaint
- STEP 2:

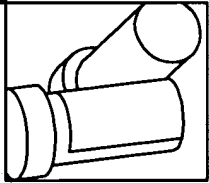

Reason for Medication
- STEP 3:

Additional important information
- STEP 4:

Review your report

Next

FIG. 7

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Who Are You?

?

1

Getting Started  
Login/Registration  
instructions  
Who are you  
Side Effects and/or  
Product Complaints

Who Are You?

Family member/spouse

Patient

Pharmaceutical Representative

Treating Physician

Other healthcare Professional

Someone else? Who?

Choose One

Choose One

Previous

Next

FIG. 8

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Adverse Event or Product Complaint?

What Do you Want to Report?

AE

Adverse Reaction or a Side Effect you are having

PC

Complaint about your medication

?

1

Getting Started  
Login/Registration  
instructions

Who are you  
Side Effects and/or  
Product Complaints

Family Members Data:

Date of Birth

06

16

70

(mm-dd-yyyy)

or

Age

1

Height

5

1

feet

6

1

inches

(ex: 5 feet 2 inches)

Weight

110

lbs

Male

Female

Pregnant ☒ YES

next

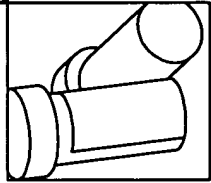
FIG. 9



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Adverse Event  
define a Symptom



- 1 Getting Started
- 2 Current Side Effects  
What Symptoms  
When Started Ended  
What Result  
What you did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

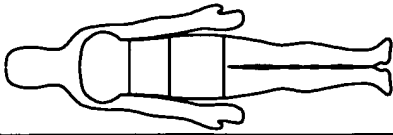
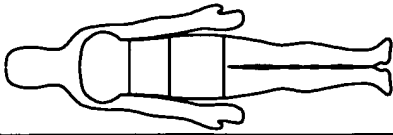
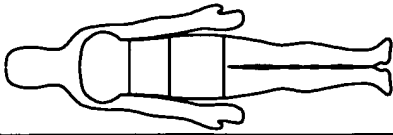

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>?</p> <p>To delete a symptom from highlight it and press Only when you have finished describing all your symptoms press</p> <p>Delete</p> <p>Done</p>												
<p>Click the region where the symptoms occurs.</p>	<table><tr><th>REGION</th><th>Which area?:</th></tr><tr><td rowspan="10"></td><td>Anus</td></tr><tr><td>Bladder</td></tr><tr><td>Buttocks</td></tr><tr><td>Cervix</td></tr><tr><td>Groin</td></tr><tr><td>Labia Minora/Majora</td></tr><tr><td>Ovaries</td></tr><tr><td>Rectum</td></tr><tr><td>Uterus</td></tr><tr><td>Vagina</td></tr></table>		REGION	Which area?:		Anus	Bladder	Buttocks	Cervix	Groin	Labia Minora/Majora	Ovaries	Rectum	Uterus
REGION	Which area?:													
	Anus													
	Bladder													
	Buttocks													
	Cervix													
	Groin													
	Labia Minora/Majora													
	Ovaries													
	Rectum													
	Uterus													
	Vagina													

FIG. 10a



To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

Delete

Done

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptoms occurs.

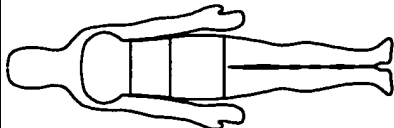
REGION

Which area?:

Right-Buttocks

Left-Buttocks

Both-Buttocks



or

- 1 Getting Started

2 Current Side Effects

What Symptoms When Started Ended

What Result What you did

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

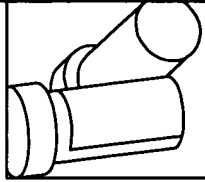
6 Review Info & Find Out More

FIG. 10b




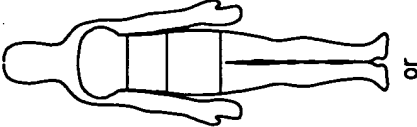
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Adverse Event  
define a Symptom

FIG. 10c

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p> <input type="button" value="Delete"/> <input type="button" value="Done"/></p> <p>To delete a symptom from highlight it and press. Only when you have finished describing all your symptoms press</p>	
<p>Click the region where the symptoms occurs.</p> 	<p>REGION Which area?:</p> <p>Buttocks</p>	<p>SYMPTOM What symptom?:</p> <p>Hip Pain</p>	<p>When did it start? <input type="text"/> (mm-dd-yyyy) When did it end? <input type="text"/> (mm-dd-yyyy) OR How Long did it last? <input type="text"/> YEAR <input type="text"/> Y it is still there? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>RESULT What was the result of this event? <input type="checkbox"/> Hospitalized under 24 Hours <input type="checkbox"/> Hospitalized over 24 Hours <input type="checkbox"/> Disability</p> <p><input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="text"/> <input type="checkbox"/> Switched Medication to <input type="text"/> <input type="checkbox"/> Did it help? <input type="checkbox"/> Took medication again and effect came back <input type="checkbox"/> Took something for it. What? <input type="text"/></p>

- 1 Getting Started
- 2 Current Side Effects  
What Symptoms  
When Started  
Ended  
What Result  
What you did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<u>General Body</u>		<input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died <input type="text"/> (mm-day-yyyy) Other <input type="checkbox"/> <input type="text"/>	Did it help? <input type="checkbox"/> YES Did something else <input type="text"/>
Add Symptom to list			

[Help](#)  
[{helpscreens}](#)

FIG. 10d

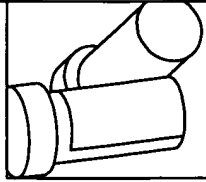




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What Medication Are You Taking?  
Medication



1 Getting Started

2 Current Side Effects

3 Current Medications

Medications  
Herbs and Supplements  
suspect Medication

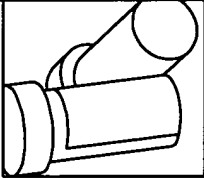
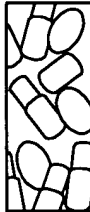
4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Your medicine Cabinet	
	<div>To delete a medication from the list highlight it and press when your current Medication list is complete press</div> <div>Delete Done</div>
Medication: Lamisil Dose: 1%  Formulation: CREAM  Frequency: 0 times a Day	<div>How Long did it last? [ ] [ ] YEAR [ ]</div> <div>Start [ ] [ ] (mm-dd-yyyy) End [ ] [ ] (mm-dd-yyyy)</div> <div>Still on it optional info Lot # of drug? if present [ ]</div> <div>What Pharmacy did you purchase it at? Name [ ] Zipcode [ ]</div> <div>Add to Medicine Cabinet</div>

FIG. 11



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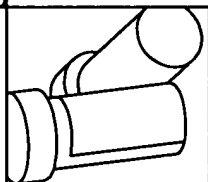
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What Medication Are You Taking?  
Suspect Medication

Please select the medication(s) that you think may have caused the event>		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
<div>Previous</div> <div>Next</div>		

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medication  
Herbs and Supplements  
suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

FIG. 12



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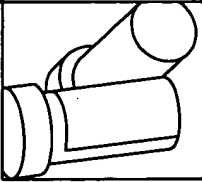
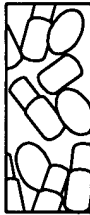
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What Medication Are You Taking?  
Herbs or Nutritional Supplements

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medications  
Herbs and Supplements  
Problem Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<p>?</p> <p>Tell us what herbs or other supplements you are taking. click letter to choose from list. ABCDEFGHIJKLM NOPQRSTUVWXYZ</p> <p>Pick one:</p> <p>Select a medication ▼</p> <p>Not on the list? Enter below</p> <p>What Dose</p> <p>Select a dose ▼</p> <p>Times a day ▼</p> <p>What Formulation?</p> <p>what formulation ▼</p>		<p>Your Current Herbs</p> <p>Your Current Medications &amp;medicine1 &amp;medicine1</p>	
<p>HOW LONG</p> <p><input type="checkbox"/> number of days ▼</p> <p>Start mm-dd-yy</p> <p>End mm-dd-yy</p> <p><input type="checkbox"/> Still on it optional info</p> <p>Lot # of supplement? if present</p> <p>What Pharmacy did you purchase it at?</p> <p>name</p> <p>zipcode</p>		<p>Add to Medicine Cabinet</p> <p>Need To delete a medication from your current list? Highlight it and press</p> <p>Delete</p> <p>when your current medication list is complete press</p> <p>Done</p>	

FIG. 13



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Adverse Event

What Are You Taking Your Medication For?

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Help

{helpscreens}

What condition are you taking your medication for? click on your medication and a list of its associated condition/disease will appear. select the appropriate one. Repeat for each medicine in the list. ?

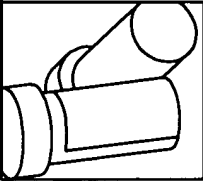
Your Medication List				Medical Condition
Medication	Formulation	Dose	Frequency (Times a day)	
Lamisil	Cream	1%	4	<div>Select only one</div> <div>Not on this list?...Enter below</div> <div></div>
<div>Previous</div> <div>Next</div>				

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FIG. 14A



FIG. 14b



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# mydrugsafety.com

Adverse Event Product Complaint  
Check your record

this Report

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Review narrative  
Review Your Info  
Other Similar Reports  
to the FDA

A - 30year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking lamisil 1% CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing}, for [indication/condition], reportedly experienced an event [verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].
The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablabla

Previous

Next

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Help

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FIG. 15



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Review Your Record  
Summary Report  
pat1 patlast



Review and Edit your report,

Report is complete

Type over text to edit and only when complete press  
A. Patient Information

Patient Name pat1 patlast  
Date of Birth 06-16-70  
Age at Event -30  
Gender ☐ Male ☐ Female  
Pregnant? ☒ Yes ☐ No ☐ Unknown  
Weight 110 Lbs  
Height 5 feet 6 inches  
(ex: 5 feet 2 inches)

☐ Died On (mm-day-yyyy)  
☐ Hospitalized Less than 24 Hrs  
☐ Hospitalized over 24 Hrs  
☒ Disability  
☐ Congenital Anomaly  
☐ Intervention needed  
☐ Life threatening  
☐ Other

Date of Event (mm-dd-yyyy)  
Date of Report 01-23-2001 (mm-dd-yyyy)

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

A. Adverse Event Results

Review narrative  
Review Your Info  
Other Similar Reports to the FDA

FIG. 16a

Description

Event Abated?

Event Reappeared?

C. Suspect Medications

Drug Name

Lamisil

1

7

Yes

No

Unknown

Yes

No

Unknown

Therapy Dates/Duration

From 07-01-2000 to 01-01-2001

Duration:1

Reason

Disease 2

Dose

1%

D. Concomitant Medication

Drug Name

Therapy Dates/Duration

Dose

Reason

Previous

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{helpscreens}

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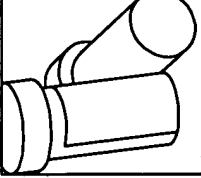
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FIG. 16b





# PatientPort



HOME | Wer wir sind | Erstmöglicher Benutzer | Datenschutz | Logout

Arzneimittel-Nebenwirkungen  
definieren Sie Das Symptom

Start

**1** Login/Registrierung  
Bedienungsanleitung  
wer sind Sie?

Arzneimittel-  
Neuwirkung oder  
Beschwerde über das  
Arzneimittel

**2** Arzneimittel-  
Nebenwirkung

Ihre Symptome  
Beginn und Ende  
Direkte Auswirkungen  
Gegenreaktionen

**3** Ihre  
Medikamente

Medikamente  
Andere Medikamente  
Heilkräuter & Vitamine

**4** Weshalb  
nehmen Sie

**FIG. 16C**

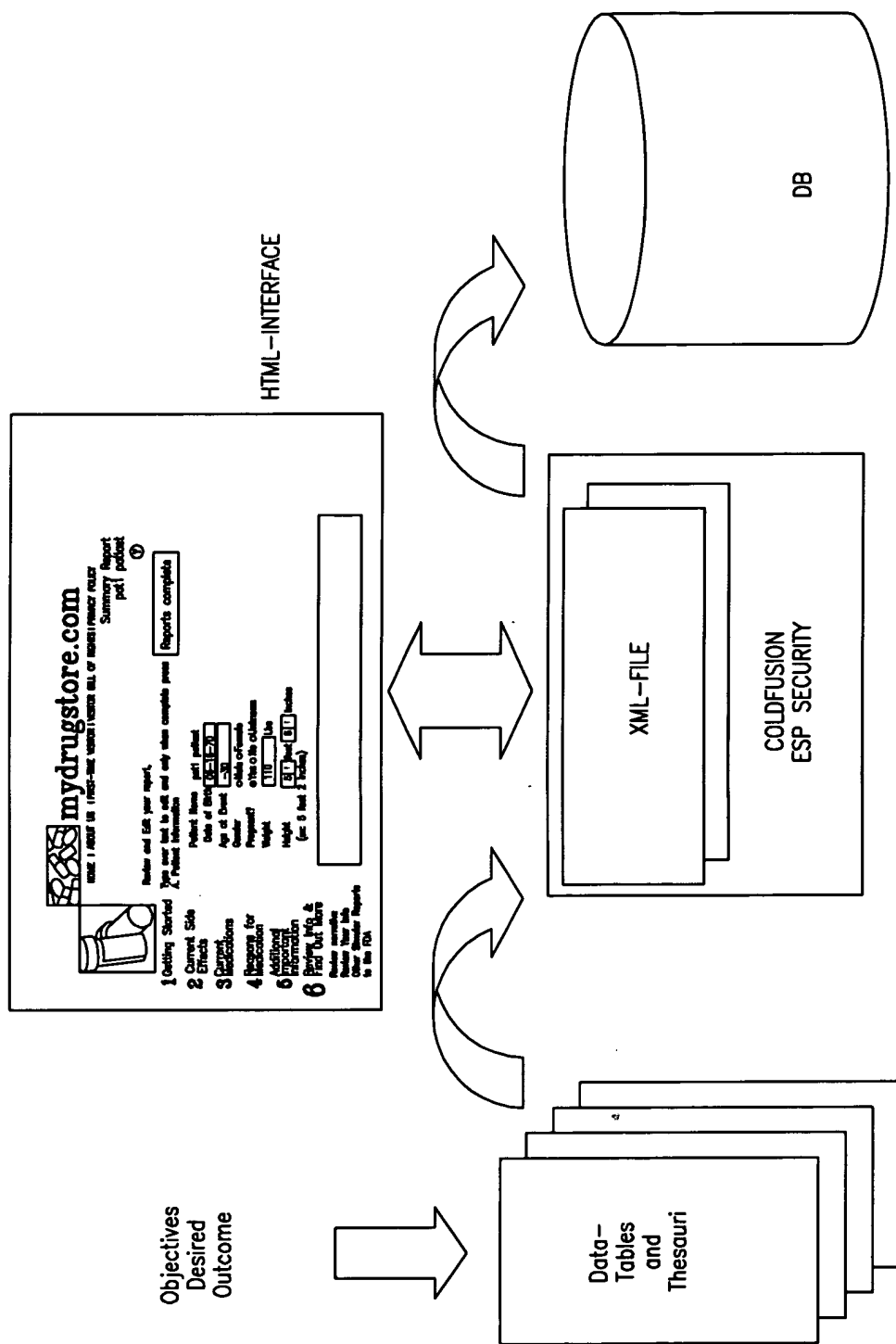
<p>Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu Beschreiben. klicken Sie bitte eine Körperteil-Region an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können Sie nachher weitere Regionen auswählen.</p>		<p>Ihre Symptome Augen, verschwommene Sicht Augen, verengte Pupillen</p>	
<p>Klicken Sie bitte die Region, in der Ihr Symptom sich ausser:</p>	<p>KOPF Wählen Sie die Region?</p>	<p>DAUER</p>	<p>WAS UNTERNAHMEN SIE DAGEGEN?</p>
	<p>AUGEN</p>	<p>Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage 1 Besteht das Symptom immer noch? <input type="checkbox"/> JA</p>	<p><input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die medikamenten Einnahme Reduzierte die medikamenten Dosis auf <input type="checkbox"/> Wechselte das Medikament auf</p>
		<p>AUSWIRKUNG DES SYMPTOMS Hat das symptom direkte medizinische Auswirkungen, wie</p>	<p>Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder</p>

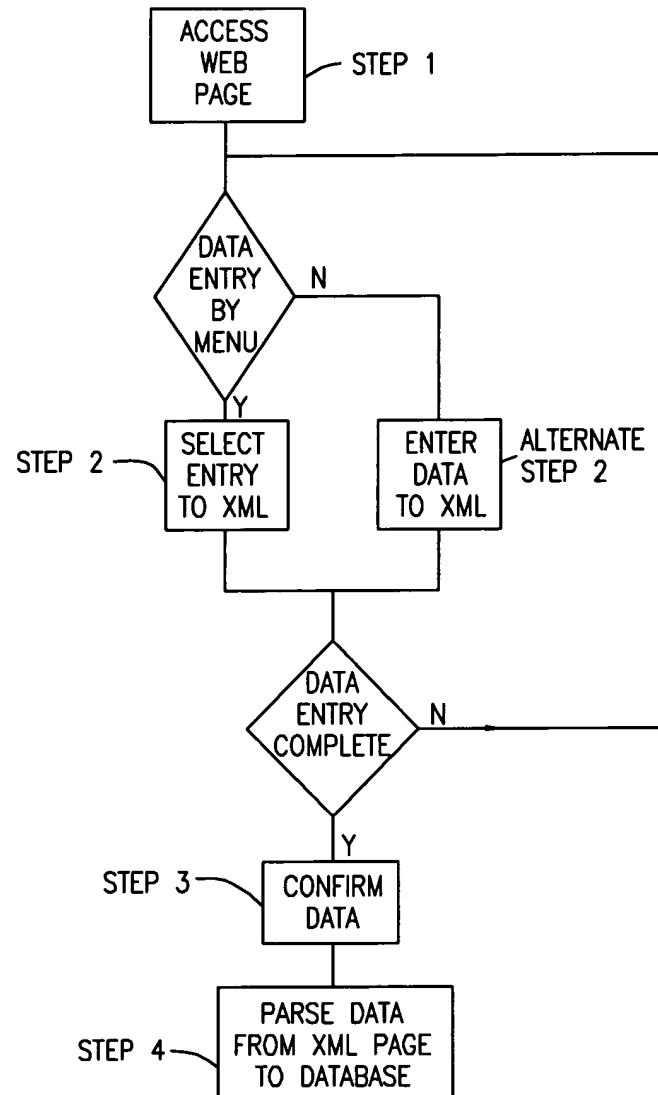
**5** Zusätzliche  
Informationen  
patienten daten  
Arzte-Daten

## 6 Bestätigen Sie Ihre Daten

Hospitalisierung unter 24 Std. <input type="checkbox"/>	Nahm ein Gegenmittel. Was? <input type="text"/>	SYMPTOM ZUR LISTE HINZUFÜGEN

FIG. 16d





*FIG. 18*